WHAT DO

BIO-WEAPONRY,

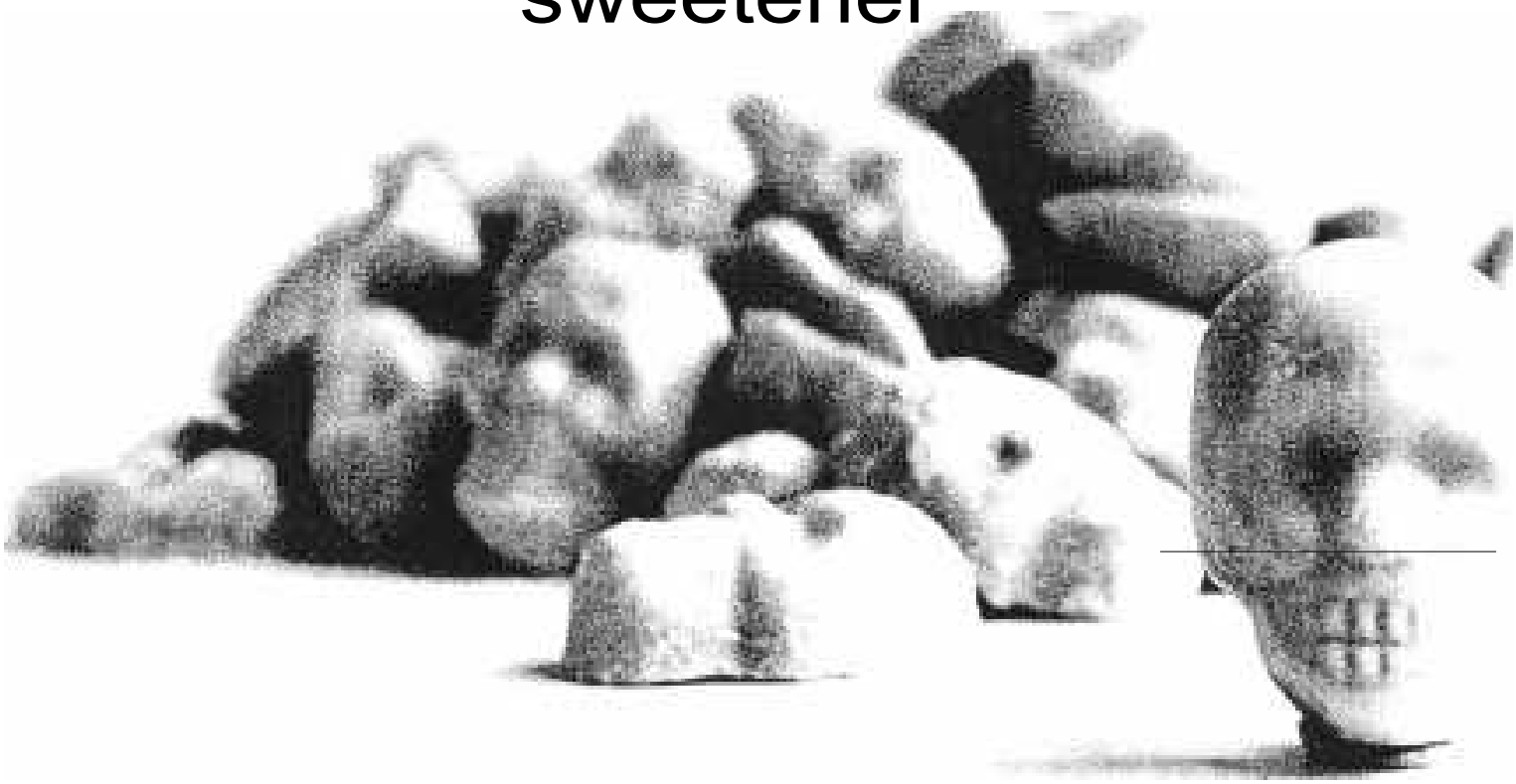
SICK MICE

AND DIET COKE

HAVE IN COMMON?

ASPARTAME

The shocking story of the world's bestselling sweetener



Aspartame

Aspartame is the most controversial food additive in history. The most recent evidence, linking it to leukaemia and lymphoma, has added substantial fuel to the ongoing protests of doctors, scientists and consumer groups who allege that this artificial sweetener should never have been released onto the market and that allowing it to remain in the food chain is killing us by degrees. **PAT** THOMAS REPORTS

Once upon a time, aspartame was listed by the Pentagon as a biochemical warfare agent. Today it's an integral part of the modern diet. Sold commercially under names like NutraSweet and Canderel, aspartame can be found in more than 5,000 foods, including fizzy drinks, chewing gum, table-top sweeteners, diet and diabetic foods, breakfast cereals, jams, sweets, vitamins, prescription and over-the-counter drugs. This means that there is a good chance that you and your family are among the two thirds of the adult population and 40 per cent of children who regularly ingest this artificial sweetener.

Because it contains no calories, aspartame is considered a boon to health-conscious individuals everywhere; and most of us, if we think about it at all, think it is safe. But independent scientists say aspartame can produce a range of disturbing adverse effects in humans, including headaches, memory loss, mood swings, seizures, multiple sclerosis and Parkinson's-like symptoms, tumours and even death.

Concerns over aspartame's toxicity meant that for eight years, the US Food and Drug Administration (FDA) denied it approval, effectively keeping it off the world market. This caution was based on compelling evidence, brought to light by numerous eminent scientists, litigators and consumer groups, that aspartame contributed to serious central nervous system damage and had been shown to cause cancer in animals. Eventually, however, political muscle, won out over scientific rigour, and aspartame was approved for use in 1981 (see timeline for details).

The FDA's about-turn opened the floodgates for aspartame's swift approval by more than 70 regulatory authorities around the world. But, as the remarkable history of the sweetener shows, the clean bill of health given to it by government regulators — whose raison d'etre should be to protect the public from harm — is simply not worth the paper it is printed on.

DECEMBER 1965
While working on an ulcer drug, a chemist at pharmaceutical manufacturer GD Searle accidentally discovers aspartame, a substance that is 180 times sweeter than sugar, yet has no calories.

1965

AUTUMN 1967
GD Searle approaches eminent biochemist Dr Harry Waisman, director of the University of Wisconsin's Joseph P Kennedy Jr Memorial Laboratory of Mental Retardation Research and a respected expert in the toxicity of phenylalanine (which comprises 50 per cent of the aspartame formula), to conduct a study of the effects of aspartame on primates. Of seven monkeys fed aspartame mixed with milk, one dies and five others have *grand* ma/ epileptic seizures.

Searle applies for FDA approval and submits over 100 studies it claims support aspartame's safety. Neither the dead monkeys nor the mice with holes in their brains are included in the submission.

Before aspartame can reach the marketplace, Dr John Olney, James Turner (attorney, consumer advocate and former 'Nader's Raider' who was instrumental in removing the artificial sweetener cyclamate from the US market), and the group Label Inc (Legal Action for Buyers' Education and Labeling) file a formal objection to aspartame's approval with the FDA, citing evidence that it could cause brain damage, particularly in children.

SPRING 1967 Searle begins safety tests, necessary for FDA approval.

Dr John Olney shows that Aspartic acid, one of aspartame's main constituents, causes holes in the brains of infant mice

Dr John Olney, professor of neuropathology and psychiatry at Washington University in St Louis School of Medicine, whose research into the neurotoxic food additive monosodium glutamate (MSG, a chemical cousin of aspartame) was responsible for having it removed from baby foods, informs Searle that his studies show that aspartic acid, one of the main constituents of aspartame, causes holes in the brains of infant mice. One of Searle's researchers, Ann Reynolds, confirms Olney's findings in a similar study.

In a memorandum, Dr Martha M Freeman of the FDA Division of Metabolic and Endocrine Drug Products criticises the inadequacy of the information submitted by Searle with particular regard to one of the compound's toxic breakdown products, diketopiperazine (DKP). She recommends that marketing of aspartame be contingent upon the sweetener's proven clinical safety.

FDA commissioner Dr Alexander Schmidt grants aspartame its first approval as a 'food additive' for restricted use in dry foods. This approval comes despite the fact that his own scientists found serious deficiencies in the data submitted by Searle.

Concerns about the accuracy of test data submitted to the FDA by Searle for a wide range of products prompt Schmidt to appoint a special task force to examine irregularities in 25 key studies for aspartame and Searle drugs Flagyl, Aldactone and Norpace.

Searle agrees to an inquiry into aspartame safety concerns. Searle withdraws aspartame from the market pending its results. The sweetener remains off the market for nearly 10 years while investigations into its safety and into Searle's alleged fraudulent testing procedures are ongoing. However, the inquiry board does not convene for another four years.

While the grand jury investigation is underway, Sidley & Austin, the law firm representing Searle, begins recruitment negotiations with Samuel Skinner, the US attorney in charge of the investigation. Skinner removes himself form the investigation and the case is passed to William Conlon.

The FDA forms a new task force, headed by veteran inspector Jerome Bressler, to further investigate irregularities in Searle's aspartame studies uncovered by the original task force. The findings of the new body will eventually be incorporated into a document known as the Bressler Report.

The Bressler Report is released. It focuses on three key aspartame studies conducted by Searle. The report finds that in one study 98 of the 196 animals died but weren't autopsied until later dates, making it impossible to ascertain the actual cause of death. Tumours were removed from live animals and the animals placed back in the study. Many other errors and inconsistencies are noted. For example, a rat was reported alive, then dead, then alive, then dead again. Bressler comments: 'The question you have got to ask yourself is: why wasn't greater care taken? Why didn't Searle, with their scientists, closely evaluate this, knowing full well that the whole society, from the youngest to the elderly, from the sick to the unsick... will have access to this product.'

The FDA creates yet another task force to review the Bressler Report. The review is carried out by a team at the FDA's Center for Food Safety and Applied Nutrition and headed by senior scientist Jacqueline Verrett.

1975

The FDA task force completes its 500-page report on Searle's testing procedures. The final report notes faulty and fraudulent product testing, knowingly misrepresented product testing, knowingly misrepresented and 'manipulated' test data, and instances of irrelevant animal research in all the products reviewed. Schmidt says: '[Searle's studies were] incredibly sloppy science. What we discovered was reprehensible.'

FDA chief counsel Richard Merrill formally requests the US Attorney's office to begin grand jury proceedings to investigate whether indictments should be filed against Searle for knowingly misrepresenting findings and 'concealing material facts and making false statements' in aspartame safety tests. This is the first time in the FDA's history that it requests a criminal investigation of a manufacturer.

Samuel Skinner leaves the US Attorney's office and takes a job with Searle's law firm. Conlon takes over Skinner's old job.

Searle hires prominent Washington insider Donald Rumsfeld as its new CEO to try to turn the beleaguered company around. A former member of Congress and defence secretary in the Ford administration, Rumsfeld brings several of his Washington colleagues in as top management.

The FDA describes the science of aspartame's manufacturer as 'incredibly sloppy', saying: 'What we discovered was reprehensible'

The FDA publishes a report exonerating Searle of any wrongdoing in its testing procedures. Jacqueline Verrett will later testify to the US Senate that her team was pressured into validating data from experiments that were clearly a 'disaster'.

Searle CEO Donald Rumsfeld vows to 'call in his markers' and use political rather than scientific means to get the FDA on side

Ronald Reagan is sworn in as president of the US. Reagan's transition team, which includes Rumsfeld, nominates Dr Arthur Hull Hayes Jr to be the new FDA commissioner.

In spite of the uncertainties over aspartame's safety in the US, aspartame becomes available, primarily in pharmaceutical products, in France. It is sold under the brand name Canderel and manufactured by the food corporation Merisant.

The journal *Medical World News* reports that the methanol content of aspartame is 1,000 times greater than most foods under FDA control. In high concentrations methanol, or wood alcohol, is a lethal poison.

The FDA's PBOI votes unanimously against aspartame's approval, pending further investigations of brain tumours in animals. The board says it 'has not been presented with proof of reasonable certainty that aspartame is safe for use as a food additive'.

1977

Despite complaints from the Justice Department, Conlon stalls the grand jury prosecution for so long that the statute of limitations on the aspartame charges runs out and the investigation is dropped. Just over a year later Conlon joins Searle's law firm, Sidley & Austin.

The FDA finally establishes a public board of inquiry (PBOI), comprising three scientists whose job it is to review the objections of Olney and Turner to the approval of aspartame and rule on safety issues surrounding the sweetener.

Canderel is now marketed throughout much of Europe (but not in the UK) as a low-calorie sweetener.

Despite complaints from the Justice Department, federal attorney William Conlon stalls a grand jury prosecution of Searle for so long that the statute of limitations runs out and the investigation is dropped

Rumsfeld states in a Searle sales meeting that he is going to make a big push to get aspartame approved within the year. Rumsfeld vows to 'call in his markers' and use political rather than scientific means to get the FDA on side.

One day after Reagan's inauguration, Searle re-applies to the FDA for approval to use aspartame as a food sweetener.

Arthur Hull Hayes Jr, appoints a five-person commission to review the PBOI's decision. Three of the five FDA scientists on it advise against approval of aspartame, stating on the record that Searle's tests are unreliable and not adequate to determine the safety of aspartame. Hayes installs a sixth member on the commission, and the vote becomes deadlocked.

The FDA approves aspartame as a tabletop sweetener and for use in tablets, breakfast cereals, chewing gum, dry bases for beverages, instant coffee and tea, gelatines, puddings, fillings, dairy -product toppings arid as a flavour enhancer for chewing gum.

Aspartame is approved for use in carbonated beverages and syrup bases in the US and, three months later, Britain. Before the end of the year Canderel tablets are launched in the UK. Granular Canderel follows in 1985.

The FDA announces that Searle has filed a petition for aspartame to be approved as a sweetener in carbonated beverages, children's vitamins and other liquids.

1981

An FDA commissioner's panel is established to review issues raised by the PBOI.

The aspartame-based sweetener Equal, manufactured by Merisant, is launched in the US.

Three out of five FDA scientists on a special commission advise against approval of aspartame, stating on the record that Searle's tests are unreliable and not adequate to determine the safety of aspartame

Hayes ignores the recommendations of his own internal FDA team, overrules the PBOI findings and gives initial approval for aspartame to be used in dry products on the basis that it has been shown to be safe for its proposed uses.

Searle attorney Robert Shapiro gives aspartame its commercial name, NutraSweet. The name is trademarked the following year. Shapiro later becomes president of Searle. He eventually becomes president and then chairman and CEO of Monsanto, which will buy Searle in 1985.

The NutraSweet Company

MONSANTO

James Turner, on behalf of himself and the Community Nutrition Institute, and Dr Woodrow Monte, Arizona State University's director of food science and nutritional laboratories, file petitions with the FDA objecting to aspartame approval based on possible serious adverse effects from the chronic intake of the sweetener. Monte also cites concern about the chronic intake of methanol associated with aspartame ingestion.

Public complaints about the adverse effects of aspartame begin to come in. The FDA requests that the US agency the Centers for Disease Prevention and Control (CDC) begins investigations of a select number of cases of adverse reactions to aspartame.

The CDC review of public complaints relating to aspartame culminates in a report, *Evaluation of Consumer Complaints Related to Aspartame* Use, which review, 213 of 592 cases and notes that re-challenge tests show that sensitive individuals consistently produce the same adverse symptoms each time they ingested aspartame. The reported symptoms include: aggressive behaviour, disorientation, hyperactivity, extreme numbness, excitability, memory loss, loss of depth perception, liver impairment, cardiac arrest, seizures, suicidal tendencies and severe mood swings. The CDC nevertheless concludes that aspartame is safe to ingest. On the same day that the CDC exonerates aspartame, Pepsi announces that it is dropping saccharin and adopting aspartame as the sweetener in all its diet drinks. Others quickly follow suit.

The first carbonated beverages containing aspartame go on sale in the US.

1983

Hayes resigns as FDA commissioner under a cloud of controversy about his taking unauthorised rides aboard a General Foods jet (General Foods was and is a major purchaser of aspartame). He serves briefly as provost at New York Medical College, and then takes a position as senior scientific consultant with Burston-Marsteller, the chief public relations firm for both Searle and Monsanto.

The FDA approves aspartame for use in multivitamins.

A study by the state of Arizona Department of Health into aspartame is published in the *Journal of Applied Nutrition.* It determines that soft drinks stored at elevated temperatures promote more rapid deterioration of aspartame into poisonous methanol.

The FDA denies Turner and Monte's requests for a hearing, noting that aspartame's critics had not presented any unresolved safety questions. Regarding aspartame's breakdown components, the FDA says that it has reviewed animal, clinical and consumption studies submitted by the sweetener's manufacturer, as well as the existing body of scientific data, and concludes that 'the studies demonstrated the safety of these components'.

On the same day that the US agency the CDC exonerates aspartame, Pepsi announces it is adopting it as the sweetener in all its diet drinks

UPI reports that 10 federal officials involved in approving aspartame have taken private sector jobs linked to the product's manufacture

Monsanto, the producer of recombinant bovine growth hormone, genetically engineered soya beans, the pesticide Roundup and many other industrial and agricultural chemicals, purchases Searle for $2.7 billion.

Turner files another citizen's petition, this time concerning the risk of seizures and eye damage from aspartame. The petition argues that medical records of 140 aspartame users show them to have suffered from epileptic seizures and eye damage after consuming products containing the sweetener and that the FDA should ban aspartame as an 'imminent hazard to the public health'.

The FDA approves aspartame for non-carbonated frozen or refrigerated concentrates and single-strength fruit juice, fruit drinks, fruit-flavoured drinks, imitation fruit-flavoured drinks, frozen stock-type confections and novelties, breath mints and tea beverages.

An FDA report on adverse reactions associated with aspartame states the majority of the complaints about aspartame, now numbering 3,133, refer to neurological effects.

1985

The US Supreme Court, headed by Justice Clarence Thomas, a former Monsanto attorney, refuses to consider arguments from the Community Nutrition Institute and other consumer groups that the FDA has not followed proper procedures in approving aspartame, and that the liquid form of the artificial sweetener may cause brain damage in heavy users of low-calorie soft drinks.

The FDA declares aspartame safe for use as an inactive ingredient, provided labelling meets certain specifications.

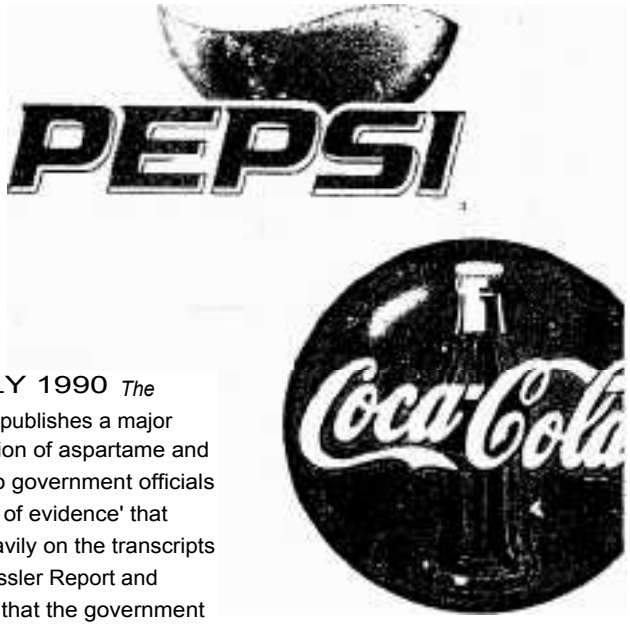
NutraSweet's aspartame patent runs out in Europe, Canada and Japan. More companies are now free to produce aspartame sweeteners in these countries.

United Press International, a leading global news-syndication organisation, reports that more than 10 federal officials involved in the decision to approve aspartame have now taken jobs in the private sector that are linked to the aspartame industry.

The FDA denies Turner's new petition, saying: 'The data and information supporting the safety of aspartame are extensive. It is likely that no food product has ever been so closely examined for safety. Moreover, the decisions of the agency to approve aspartame for its uses have been given the fullest airing that the legal process requires.'

A US Senate hearing is held to address the issue of aspartame safety and labelling. The hearing reviews the faulty testing procedures and the 'psychological strategy' used by Searle to help ensure aspartame's approval. Other information that comes to light includes the fact that aspartame was once on a Pentagon list of prospective biochemical-warfare weapons.

Numerous medical and scientific experts testify as to the toxicity of aspartame. Among them is Verrett, who reveals that, while compiling its 1977 report, her team was instructed not to comment on or be concerned with the overall validity of the studies. She states that questions about birth defects have not been answered. She also states that increasing the temperature of the product leads to an increase in production of DKP, a substance shown to increase uterine polyps and change blood cholesterol levels. Verrett comments: 'It was pretty obvious that somewhere along the line, the bureau officials were working up to a whitewash.'



20 JULY 1990 *The Guardian* publishes a major investigation of aspartame and delivers to government officials 'a dossier of evidence' that draws heavily on the transcripts of the Bressler Report and demands that the government review the safety of aspartame. No review is undertaken. *The Guardian* is taken to court by Monsanto and forced to apologise for printing its story.

TheGuardian

1992 NutraSweet signs agreements with Coca-Cola and Pepsi stipulating that it is their preferred supplier of aspartame.

1987

The FDA has received more than 4,000 complaints from consumers about adverse reactions to the sweetener.

1991 Britain's National Institutes of Health publishes *Adverse Effects of Aspartame: January '86 through December* '90, a bibliography of 167 studies documenting adverse effects associated with aspartame.

20 JANUARY 199
The FDA approves aspartame for use in malt beverages, breakfast cereals, and refrigerated puddings and fillings and in bulk form (in large packages like sugar) for tabletop use. NutraSweet markets these bulk products under the name 'NutraSweet Spoonful'.

14 DECEM
BER 1992 NutraSweet's US patent for aspartame expires, opening up the market for other companies to produce the substance.

Dr HJ Roberts, director of the Palm Beach Institute for Medical Research, claims that several recent aircraft accidents involving confusion and aberrant pilot behaviour were caused by ingestion of products containing aspartame.

It is reavealed during a Senate hearing that aspartame was once on a Pentagon list of prospective biochemical-warfare weapons

19 APRIL 1993

The FDA approves aspartame for use in hard and soft candies, non-alcoholic flavoured beverages, tea beverages, fruit juices and concentrates, baked goods and baking mixes, and frostings, toppings and fillings for baked goods.

APRIL 1995 Consumer activist, and founder of anti-aspartame group Mission Possible, Betty Martini uses the US's Freedom of Information Act to force the FDA to release an official list of adverse effects associated with aspartame ingestion. Culled from 10,000 consumer complaints, the list includes four deaths and more than 90 unique symptoms, a majority of which are connected to impaired neurological function. They include: headache; dizziness or problems with balance; mood change; vomiting and nausea; seizures and convulsions; memory loss; tremors; muscle weakness; abdominal pains and cramps; change in vision; diarrhoea; fatigue and weakness; skin rashes; deteriorating vision; joint and musculoskeletal pain.

By the FDA's own admission, fewer then 1 per cent of those who have problems with something they consume ever report it to the FDA. This means that around 1 million people could have been experiencing adverse effects from ingesting aspartame.

27 **JUNE 1996**

The FDA removes all restrictions from aspartame use, and approves it as a 'general-purpose sweetener', meaning that aspartame can now be used in any food or beverage.

NOVEMBER 1996

Drawing on data compiled by the US National Cancer Institute's Surveillance, Epidemiology and End Results programme, which collects and distributes data on all types of cancer, Olney publishes peer-reviewed research in the *Journal of Neuropathology* ***and Experimental Neurology.*** It shows that brain-tumour rates have risen in line with aspartame consumption and that there has been a significant increase in the conversion of less deadly tumours into much more deadly ones.

28 FEBRUARY 1994

Aspartame now accounts for the majority (75 per cent) of all the complaints in the US adverse-reaction monitoring system. The US Department of Health and Human Services compiles a report that brings together all current information on adverse reactions attributed to aspartame. It lists 6,888 complaints, including 649 reported by the CDC and 1,305 reported by the FDA.

12 JUNE 1995 The FDA announces it has no further plans to continue to collect adverse reaction reports or monitor research on aspartame.

DECEMBER 1996 The results of a remarkable study conducted by Dr Ralph G Walton, professor of clinical psychology at Northeastern Ohio Universities, are revealed. Commissioned by the hard-hitting US national news programme 60 Minutes, it sheds some light on the absurdity of aspartame-safety studies. Walton reviewed 165 separate studies published in the preceding 20 years in peer-reviewed medical journals. Seventy-four of the studies were industry-funded, all of which attested to aspartame's safety. Of the other 91 non-industry funded studies, 84 identified adverse health effects. Six of the seven non-industry funded studies that were favourable to aspartame were from the FDA, which has a public record of strong pro-industry bias. To this day, the industry-funded studies are the ones that are always quoted to the press and in official rebuttals to aspartame critics. They are also the studies given the greatest weight during the approval process and in official safety reviews.

John Olney shows that brain-tumour rates have risen in line with aspartame consumption and that there has been a significant increase in the conversion of less deadly brain tumours to much more deadly ones

10 FEBRUARY 1998
Monsanto petitions the FDA for approval of a new tabletop sweetener called Neotame. It is around 60 times sweeter than aspartame and up to 13,000 times sweeter than sugar. Neotame is less prone to breaking down in heat and in liquids than aspartame because of the addition of 3,3-dimethylbutyl, a poorly studied chemical with suspected neurotoxic effects. Strengthening the bond between aspartame's main constituents eliminates the need for a health warning directed at people suffering from PKU.

OCTOBER 1998 The UK's Food Commission publishes two surveys on sweeteners. The first shows that several leading companies, including St Wei, Muller and Sainsbury's, have ignored the legal requirement to state 'with sweeteners' next to the name of the product. The second reveals that aspartame not only appears in 'no-sugar added' and 'light' beverages but also in ordinary non-dietetic drinks because it's three times cheaper than ordinary sugar.

20 **JUNE** 1999 An investigation by *The Independent on Sunday* reveals that aspartame is made using a genetic engineering process. Aspartame component phenylalanine is naturally produced by bacteria. The newspaper reveals that Monsanto has genetically engineered the bacteria to make them produce more phenylalanine. Monsanto claims that the process had not been revealed previously because no modified DNA remains in the finished product, and insists that the product is completely safe; though scientists counter that toxic effects cannot be ruled out in the absence of long-term studies .
A Monsanto spokeswoman says that while aspartame for the US market is often made using genetic engineering, aspartame supplied to British food producers is not. The extent to which US brands of low-calorie products containing genetically engineered aspartame have been imported into Britain is unclear.

An investigation by *The Independent on Sunday* reveals that aspartame is made using a genetic engineering process

1998

Independent scientists from the University of Barcelona publish a landmark study clearly showing that aspartame is transformed into formaldehyde in the bodies of living specimens (in this case rats), and that this formaldehyde spreads throughout the specimens' vital organs, including the liver, kidneys, eyes and brain. The results fly in the face of manufacturers' claims that aspartame does not break down into formaldehyde in the body, and bolster the claims of aspartame critics that many of the symptoms associated with aspartame toxicity are caused by the poisonous and cumulative effects of formaldehyde.

February 8 1999
Monsanto files a petition with the FDA for approval of the general use of Neotame.

MAY 2000 Monsanto, under pressure - not least from the worldwide resistance to genetically manipulated food and ongoing lawsuits - sells NutraSweet to JW Childs Associates, a private-equity firm comprised of several former Monsanto managers, for $440m. Monsanto also sells its equity interest in two European sweetener joint ventures, NutraSweet AG and Euro-Aspartame SA.

December 10 2001

The UK's Food Standards Agency requests that the European Commission Scientific Committee on Food conducts an updated review of aspartame. The committee is asked to look carefully at more than 500 scientific papers published between 1988 and 2000 and any other new scientific research not examined previously.

9 JULY 2002 The FDA approves the tabletop and general use of Neotame. The 'fast-track' approval raises eyebrows because, historically, the FDA takes at least 10 years to approve food additives. Neotame is also approved for use in Australia and New Zealand, but has yet to be approved in the UK.

MAY 2004 The feature-length documentary Sweet *Misery* is released on DVD **(see www.soundandfuryproductions.com).** Part-documentary, part-detective story, it includes interviews with people who have been harmed by aspartame, as well as credible testimony from advocates, doctors, lawyers and long-time campaigners, including James Turner, Hi Roberts and renowned neurosurgeon Dr Russell Blaylock. (UK orders: Namaste Publishing, info@namastepublishing.co.uk.)

19 FEBRUARY 2003 Members of the European Parliament's Environment, Public Health and Consumer Policy Committee approve the use of sucralose (see page 50) and an aspartame-acesulfame salt compound (manufactured in Europe by the aspartame-producing Holland Sweetener Company and sold under the name Twinsweet), agreeing to review of the use of both in three years' time. At the same time, a request by European greens that the committee re-evaluate the safety of aspartame and improve the labelling of aspartame-containing products is rejected.

SEPTEMBER 2004 US consumer group the National Justice League files a $350m class action lawsuit against the NutraSweet Corporation (the current owner of aspartame products), the American Diabetes Association and Monsanto. Some 50 other defendants have yet to be named, but mentioned throughout the lawsuit is the central role of Donald Rumsfeld in helping to get aspartame approved through the FDA. The plaintiffs maintain that this litigation will prove how deadly aspartame is when it is consumed by humans. Little progress has been made so far in bringing the action to court.

2002

10 DECEMBER 2002 The European Commission Scientific Committee on Food publishes its final report on aspartame. The 24-page report largely ignores independent research and consumer complaints, relying instead on frequently cited articles in books and reviews put together by employees or consultants of aspartame manufacturers. When independent research is cited, it is generally refuted with industry-sponsored data. An animal study showing aspartame's disruption of brain chemistry, a human study linking aspartame to neurophysiological changes that could increase seizure risk, another linking aspartame use with depression in individuals susceptible to mood disorder, and two others linking aspartame ingestion with headaches are all dismissed. The report's conclusion amounts to a single sentence: 'The committee concluded that... there is no evidence to suggest that there is a need to revise the outcome of the earlier risk assessment or the [acceptance daily intake] previously established for aspartame.'
As with the FDA, there are concerns about the neutrality of some of the committee's members and their links with the International Life Sciences Institute (ILSI), an industry group that funds, among other things, research into aspartame. ILSI members include Monsanto, Coca-Cola and Pepsi.

2005

The Ramizzini Institute in Bologna, a non-profit, private institution set up to research the causes of cancer, releases the results of a very large, long-term animal study into aspartame ingestion. Its study shows that aspartame causes lymphomas and leukaemia in female animals fed aspartame at doses around 20 milligram per kilogram of body weight, or around half the accepted daily intake for humans.

MARCH 200 5 The NutraSweet Company reopens its plant in Atlanta, Georgia, (dormant since 2003) in order to meet increased demand for its sweetener. Aspartame, sold commercially as NutraSweet, Equal, Equal-Measure, Spoonful, Canderel and Benevia, is currently available in more than 100 countries and used in more than 5,000 products by at least 250 million people every day. Worldwide, the aspartame industry's sales amount to more than $1 billion yearly. The US is the primary consumer.

a significant spike in blood-plasma levels of aspartate after the administration of aspartame in liquids. Too much aspartate in the brain produces free radicals,. unstable molecules that damage and kill brain cells.

Humans are five times more sensitive to the effects of aspartic add (as well as glutamic acid, found in MSG) than rodents, and 20 times more sensitive than monkeys, because we concentrate these excitatory amino acids in our blood at much higher levels and for a longer period of time. Aspartic acid has a cumulative harmful effect on the endocrine and reproductive systems. Several animal experiments have shown that excitotoxins can penetrate the placental barrier and reach the foetus.

In addition, as levels of aspartic acid rise in the body so do levels of the key neurotransmitter norepinephrine (also known as noradrenaline), a 'stress hormone' that affects parts of the human brain where attention and impulsivity are controlled. Excessive norepinephrine is associated with symptoms such as anxiety, agitation and mania.

METHANOL

Methanol (wood alcohol) comprises 10 per cent of aspartame. It is a deadly poison that is liberated from aspartame at temperatures in excess of 86° Fahrenheit (30° centigrade) – for instance, during storage or inside the human body. The US Environmental Protection Agency considers methanol a 'cumulative poison due to the low rate of excretion once it is absorbed', meaning that even small amounts in aspartame-containing foods can build up over time in the body.

The most well known problems from methanol poisoning are vision disorders, including misty or blurry vision, retinal damage and blindness. Other symptoms include headaches, tinnitus, dizziness, nausea, gastrointestinal disturbances, weakness, vertigo, chills,. memory lapses, numbness and shooting pains in the extremities behavioural disturbances, and neuritis.

The EPA tightly controls methanol exposure, allowing only very minute levels to be present in foods or-in environmental exposures. But Blaylock says: 'The level allowed in NutraSweet is seven times the amount that the EPA will allow anyone else to use.'

FORMALDEHYDE

The methanol absorbed from aspartame is converted to formaldehyde in the liver. Formaldehyde is a neurotoxin and known carcinogen. It causes retinal **damage** and birth defects, interferes with DNA replication, and has been shown to cause squamous-cell carcinoma, a form of skin cancer, in animals. Several human studies have found that chronic, low-level formaldehyde exposure has been linked with a variety of symptoms, including headaches, fatigue, chest tightness, dizziness, nausea, poor concentration and seizures.

FORMIC ACID

Formic acid is a cumulative poison produced by the breakdown of formaldehyde. It concentrates in the brain, kidneys, spinal fluid and other organs, and is highly toxic to cells. Formic acid can lead to accumulation of excessive acid in the body fluids – a condition known as acidosis. The small amounts of formic acid derived from the methanol absorbed from aspartame may or may not be dangerous; there are no human or mammalian studies to enlighten us.

TIME FOR ACTION

The story of aspartame is the story of the triumph of corporate might over scientific rigour. It shines a spotlight on the archaic and unbalanced procedure for approving food additives.

We ingest food additives daily, yet their approval does not require the same scientific thoroughness as drug approval; and, unlike drugs, there is no requirement for surveillance of adverse effects that crop up once the additive is in use.

Approval does not involve looking at what people are already eating and whether the proposed substance will interact with other additives. Nor does it take into account whether the additive exacerbates damage caused by other aspects of the modern lifestyle (for instance, the neurological damage caused by pesticide ingestion or exposure). Nor does it look for subtle chronic effects (for instance, the gradual build-up of methanol in the body with regular aspartame ingestion).

There are other problems. Most studies into aspartame are animal studies; which are notoriously difficult to relate to humans. So why bother performing them in the first place? The answer is, manufacturers and regulators use animal research as a double-edged sword. If an animal study reveals no evidence of harm, the manufacturer can use it to support its case. If it reveals harm, however, the manufacturer is free to flip-flop into the argument that the results of animal studies are inconclusive in relation to humans. Faced with inconclusive evidence regulators will always err on the side of the manufacturer, who has after all demonstrated proper bureaucratic procedure by funding and submitting its animal tests for consideration.

The approval process for any substance that humans put in their mouths on a daily basis should be based on solid human data and on the precautionary principle when such data is not available. But, as it stands, the regulation of food additives in the US, the UK and elsewhere leaves the burden of proof of harm on average people, despite the fact that most of us are either too detached or too timid to complain or simply don't have the energy to take on multinational corporations.

The history of aspartame is all the more remarkable because of the number of motivated people who have refused to accept the mantra 'if it's approved by the government it must be safe'. Nearly every piece of independent research shows the outrage of these people, who have had to withstand threats of litigation and being vilified in the media as 'hysterics', is justified.

After 30 years of aspartame's commercial success, it would be easy to conclude it is too late to act. And yet earlier this year hundreds of products were swept off supermarket shelves on the chance that they might have contained minuscule amounts of a potentially carcinogenic dye, Sudan 1. No studies existed to show that Sudan 1 *could* cause cancer in humans. The likelihood of any one person's exposure to Sudan 1 being high enough to produce a tumour was minute. Nevertheless, on the basis of the precautionary principle, action was taken.

Aspartame is not a life-saving drug. It is not even a very effective diet aid, as shown by widespread obesity in the West. Until the many concerns about it have been examined in 'corporate-neutral', large-scale, long-term, randomised, double-blind, placebo-controlled human trials (the gold standard of scientific proof) it should be taken out of our food.

LIFE AFTER ASPARTAME

Aspartame should never have reached the marketplace. But even if the authorities were to remove it from sale tomorrow, how much faith should consumers place in the other artificial sweeteners on the market? PAT **THOMAS** REPORTS

There is not a single artificial sweetener on the market that can claim, beyond all reasonable doubt, to be safe for humans to consume. Saccharin, cyclamate and acesulfame-K have all been show to cause cancer in animals. Even the family of relatively benign sweeteners known as polyols, such as sorbitol and mannitol, can cause gastric upset if eaten in quantity.

NutraSweet believes that its new aspartame-based sweetener, Neotame, is 'revolutionary'; but, seemingly, it is only a more stable version of aspartame. This leaves the market wide open for sucralose.

Sucralose, sold commercially as Splenda, was discovered in 1976 by researchers working for British sugar refiner Tate & Lyle. Four years later, Tate & Lyle joined forces with Johnson & Johnson to develop and commercialise sucralose under the auspices of a new company, McNeil Specialty Products (now called McNeil Nutritionals). Sucralose has been approved by more than 60 regulatory bodies throughout the world, and is now in more than 3,000 products worldwide. In the ITS, Coca-Cola has developed a new diet drink sweetened with Splenda, and other major soft drink manufacturers are expected to follow suit.

> ...if sucralose is so safe, why does manufacturer Tate & Lyle have such a fervent need to suppress any criticism of it?

Splenda has had to rethink it's slogan "made from sugar, so it tastes like sugar" in the wake of a heated US legal challenge and a recent ruling by the New Zealand Advertising Standards Authority that said it confused and mislead consumers. While it is true that sugar, or sucrose, is one of the starting materials for sucralose, its chemical structure is significantly different from that of sucrose.

In a complex chemical process, the sucrose is processed with, among other things, phosgene (a chemical-warfare agent used during WW1, now a common intermediary in the production of plastics, pesticides and dyes), and three atoms of chlorine are selectively substituted for three hydroxyl (hydrogen and oxygen) groups naturally attached to the sugar molecule.

This process produces 1,6-dichloro-1,6-dideoxy-beta-D-fructofuranosyl-4-chloro-4-deoxy-alpha-D-galactopyranoside (also known as trichlorogalactosucrose or sucralose), a new chemical substance which Tate & Lyle calls a 'water-soluble chlorocarbohydrate'.

Accepting Tate & Lyle's classification of sucralose as a chlorocarbohydrate at face value raises reasonable concerns about its suitability as a food additive. Chlorinated carbohydrates belong to a class of chemicals known as chlorocarbons. This class of chemicals includes a number of notorious human and environmental poisons, including polychlorinated biphenyls (PCBs); aliphatic chlorinated carbohydrates; aromatic chlorinated carbohydrates such as DDT; organochlorine pesticides such as aldrin and dieldrin; and aromatic chlorinated ethers such as polychlorinated dioxins (PCDD) and polychlorinated dibenzofurans (PCDF).

Most of the synthetic chlorinated compounds that we ingest, such as the pesticide residues in our food and water, bio-accumulate slowly in the body; and many cause developmental problems in the womb or are carcinogenic. How do we know that sucralose is any different?

Tate & Lyle insists that sucralose passes through the body virtually intact, and that the tight molecular bond between the chlorine atoms and the sugar molecule results in a very stable and versatile product that is not metabolised in the body for calories. This doesn't mean, however, that sucralose is not metabolised in the body at all, and critics

like HJ Roberts argue that, during storage and in the body, sucralose breaks down into among other things 1,6 dichlorofructose, a chlorinated compound that has not been adequately tested in humans.

Tate & Lyle maintains that sucralose and its breakdown products have been extensively tested and proven safe for human consumption. The company notes that in seeking approval from the US Food and Drug Administration (FDA), McNeil Specialty Products submitted more than 110 studies that attested to the safety of sucralose.

BUT CAN CONSUMERS TRUST THIS RESEARCH DATA?

The vast majority of studies submitted to the FDA were unpublished animal and laboratory studies performed by Tate & Lyle itself, and therefore liable to charges of potentially unacceptable bias. Only five involved human subjects, and these were short-term, often single-dose, studies that clearly could not adequately reflect the expected real-world usage of sucralose. After questions were raised by the FDA about the safety of sucralose for diabetics, and prior to approval, a further five human studies were eventually submitted. On 1 April 1998 the FDA approved sucralose for limited uses; one year later it approved it as a general-purpose sweetener.

Some questions about sucralose's safety, arising from the data submitted to the FDA, remain unanswered. These studies included unsettling findings about animals, which, when exposed to high doses of sucralose, experienced:

shrunken thymus and spleen;
enlarged liver and kidneys; and
reduced growth rate in adults and newborns.

In the FDA's 'final-rule' report, several of the studies submitted by McNeil were found to have 'inconclusive' results or were 'insufficient' to draw firm conclusions from them. These included:

- a test that examined the clastogenic activity (ability to break chromosomes apart) of sucralose, and a test that looked for chromosomal aberrations in human lymphocytes exposed to sucralose';
- a series of three animal genotoxicity studies; and
- laboratory studies using lymphoma tissue from mice which showed that sucralose was 'weakly mutagenic' (capable of causing cellular mutations).

Clastogenic, genotoxic and mutagenic substances are all potential risk factors. in the development of cancer.

In addition to these, three studies that looked at very specific 'anti-fertility' effects of sucralose and its breakdown products, especially with regard to sperm production were also deemed insufficient; this is particularly worrying, since other 'chlorosugars', such as 6-chloroglucose, are currently being studied as anti-spermatogenic drugs.

Furthermore, the administration observed that McNeil had failed to explain satisfactorily a reduction in body weight seen in animals fed sucralose and that 'additional study data were needed to resolve this issue'. Ironically for a product that 'tastes like sugar', McNeil argued that weight loss was due to the 'reduced palatability of sucralose-containing diets'. FDA reviewers also found that at mid to high doses there was a trend towards 'decreasing white blood cell and lymphocyte counts with increasing dose levels of sucralose'. This was dismissed as having no 'statistical significance' by the FDA; in healthy animals and humans this may be so, but what happens when already immune-compromised individuals ingest sucralose?

Tate & Lyle says that any lingering concerns about sucralose are unfounded and that only a small amount, 15-20 per cent, of sucralose is absorbed and broken down in the human gut. The rest passes through the body unmetabolised and is excreted in urine and faeces. This in itself provokes important questions.

What happens to sucralose that is flushed down the toilet? Does it remain stable or react with other substances (for instance, the chlorine used in water-treatment plants, or microbial life) to form new compounds?

Is sucralose or any resulting chemical compound it may form safe for the environment? Is it harmful to aquatic life or wild animals?

Will sucralose begin to appear in our water supply, in the way that certain drugs have, silently increasing our exposure to it? And would that increased exposure be safe?

PUBLISH AND BE SUED

In the face of emerging public criticism, lawyers for Tate & Lyle are already gearing up for a battle. According to attorney James Turner, a key player in the aspartame drama, 'there's going to be a huge fight about Splenda in the next few months... [Tate & Lyle's] lawyers are already on the case trying to shut everybody up'.

It's a tactic that worked well for Monsanto, which certainly used legal pressure against anyone who criticised NutraSweet Recently, the publisher of the local newspaper the *Brighton Argus* considered it prudent to publish an apology composed by Tate & Lyle (or their lawyers) or face a legal action for defamation and loss of sales after printing an article suggesting that sucralose was harmful to humans.

Tate & Lyle's first high-profile victim, however, was mercola.com — one of the world's most visited internet health sites. Run by Dr Joseph Mercola, the site has been a vocal critic of sucralose for years. Instead of carrying freely available information on sucralose that might stimulate spirited public debate, it now carries the following message: 'Attorneys acting on behalf of the manufacturers of sucralose, Tate & Lyle Plc, based in London, England, have requested that the information contained on this page not be made available to internet users in England.'

At this point, concerned consumers should be asking themselves several questions. Does the story of sucralose sound familiar? If sucralose is safe beyond any reasonable doubt, why is there such a fervent need to suppress any criticism of it? Finally, whom do such tactics really serve? Do they serve the consumer and the principles of choice, information, safety and redress? Or do they serve the corporate machine and its need to keep generating profits without taking responsibility for the human cost of doing so?

cooperation is needed to establish a common language and standards, said Cal Slemp, vice-president and global leader for security and privacy services at IBM Global Services.

The common language for exchanging user access information is also known as federated IAM.

"Governments have a huge part to play in this, because they have ultimate responsibility for their citizens, and depending on the country they may have ultimate responsibility for the businesses and e-commerce as well," Slemp said.

What's missing right now, he noted, is a trusted third party to authenticate trustworthiness. "So we've got inconsistent and incomplete implementation [in individual countries], and also no standard approach to the future nor a target to shoot at."

Slemp believes that now is the right time to establish a global body that will consider the interests of all countries and build up a foundation, which the individual countries can expand upon to fulfil their unique requirements.

"There are organisations that work together on this issue and issues like that across borders all the time, and it can be as grandiose as to say the UN has a process in place to share information like that and create working groups to try to create standards or expectations and across multiple jurisdictions," said Slemp. "I just don't know what the name would be."

(Source: ZDNet Asia, November 10, 2005)

HYPERBARIC OXYGEN MOBILISES STEM CELLS

A study, to be published in the April 2006 edition of the *American Journal of Physiology – Heart and Circulatory Physiology*, reveals that hyperbaric oxygen treatments increase by eightfold the number of stem cells circulating in a patient's body. Stem cells, also called progenitor cells, are crucial to injury repair.

Stem cells exist in the bone marrow of human beings and animals and are capable of changing their nature to become part of many different organs and tissues. In response to injury, these cells move from the bone marrow to the injured sites, where they differentiate into cells that assist in the healing process.

The movement, or mobilisation, of stem cells can be triggered by a variety of stimuli including pharmaceutical agents as well as hyperbaric oxygen treatments.

(Source: via http://www.eurekalert.org/pub_releases/2005-12/cops-p sf122805.php)

BRITISH MP CALLS FOR URGENT BAN ON ASPARTAME

A member of the parliamentary select committee on food and the environment yesterday called for emergency action to ban the artificial sweetener aspartame, used in 6,000 food, drink and medicinal products.

The Liberal Democrat MP Roger Williams said in an adjournment debate in the Commons that there was "compelling and reliable evidence for this carcinogenic substance to be banned from the UK food and drinks market altogether". In licensing aspartame for use, regulators around the world had failed in their main task of protecting the public, he told MPs.

Mr Williams highlighted new concerns about the additive's safety, raised by a recent Italian study that linked aspartame to cancer in rats. He said the history of aspartame's licensing put "regulators and politicians to shame", with the likes of Donald Rumsfeld, the US defence secretary and former head of Searle, the company that discovered the sweetener, "calling in his markers" to get it approved.

Responding for the government, the public health minister, Caroline Flint, said a thorough independent review of safety data had been conducted as recently as 2001 and the Food Standards Agency advice remained the same: aspartame is safe for use in food. She said the government took food safety very seriously.

"1 am advised that aspartame does not cause cancer," she said, adding that artificial sweeteners also help to control obesity.

The European Food Safety Authority would be reviewing the Italian study as soon as it had full data on it, but an initial review by the UK's expert committee on toxicity had not been convinced by its authors' interpretation of their data.

Aspartame is now consumed on average every day by one in 15 people worldwide, most of whom are children, according to the MP. It is used to sweeten no fewer than 6,000 products, from crisps, confectionery, chewing gums, diet and sports drinks to vitamin pills and medicines, including those for children. Yet the science that supported its approval was "biased, inconclusive and incompetent".

Mr Williams said he was using the immunity he was afforded under parliamentary privilege to initiate a debate about aspartame's safety, which had been largely repressed since the early 1980s with the help of the sweetener industry's lawyers.

Independent research published in November by the European Ramazzini Foundation showed that moderate regular consumption of aspartame led to a repeated incidence of malignant tumours in rats and "should have set alarm bells ringing in health departments around the world", said Mr Williams. "The World Health Organization recognises such findings in rats as being highly predictive of a carcinogenic risk for humans. The contrast between the quality of the science in the Ramazzini study and the industry studies could not be more clear and more damaging to the industry."

Mr Williams, the MP for Brecon and Radnorshire and a Cambridge science graduate, said he had been looking into the safety of aspartame for more than *a year.* At first he had been unconvinced by the "internet conspiracy theories", but he said that what he had found "truly horrified" him. Sound science and proper regulatory and political independence had been notable by their absence in the approval of aspartame, he said. In addition to Mr Rumsfeld being instrumental in securing aspartame's approval with the support of the then newly elected US president Ronald Reagan, there had been numerous examples of decision-makers who were worried about aspartame's safety being discredited or removed from their positions. Industry sympathisers had been appointed to replace them and, in turn, were recompensed with lucrative jobs working for the sweetener industry.

The European Food Safety Authority said last night [December 14] that it planned to review the safety of aspartame as "a matter of high priority" in the light of the Ramazzini Foundation study. The foundation's director, Dr Morando Soffritti, said he expected to send the authority a 1,000-page dossier by the end of the month.

The industry's Aspartame Information Service said Mr Williams's material brought no new information to the public. "The minister's response was accurate and on point", according to a statement.

(Source: By Felicity Lawrence, The Guardian, *UK, December 15, 2005)*